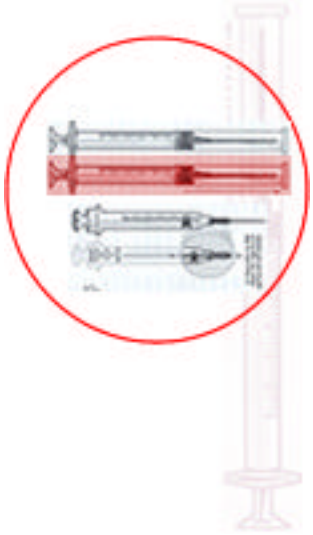
NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries. Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities are required to use safer medical devices.

SAFER MEDICAL DEVICE IMPLEMENTATION IN HEALTH CARE FACILITIES

SHARING LESSONS LEARNED

NIOSH has asked a small number of health care facilities to share their experiences on how they implemented safer medical devices in their settings. These facilities have agreed to describe how each step was accomplished, and also to discuss the barriers they encountered and how they were resolved, and most importantly, lessons learned.

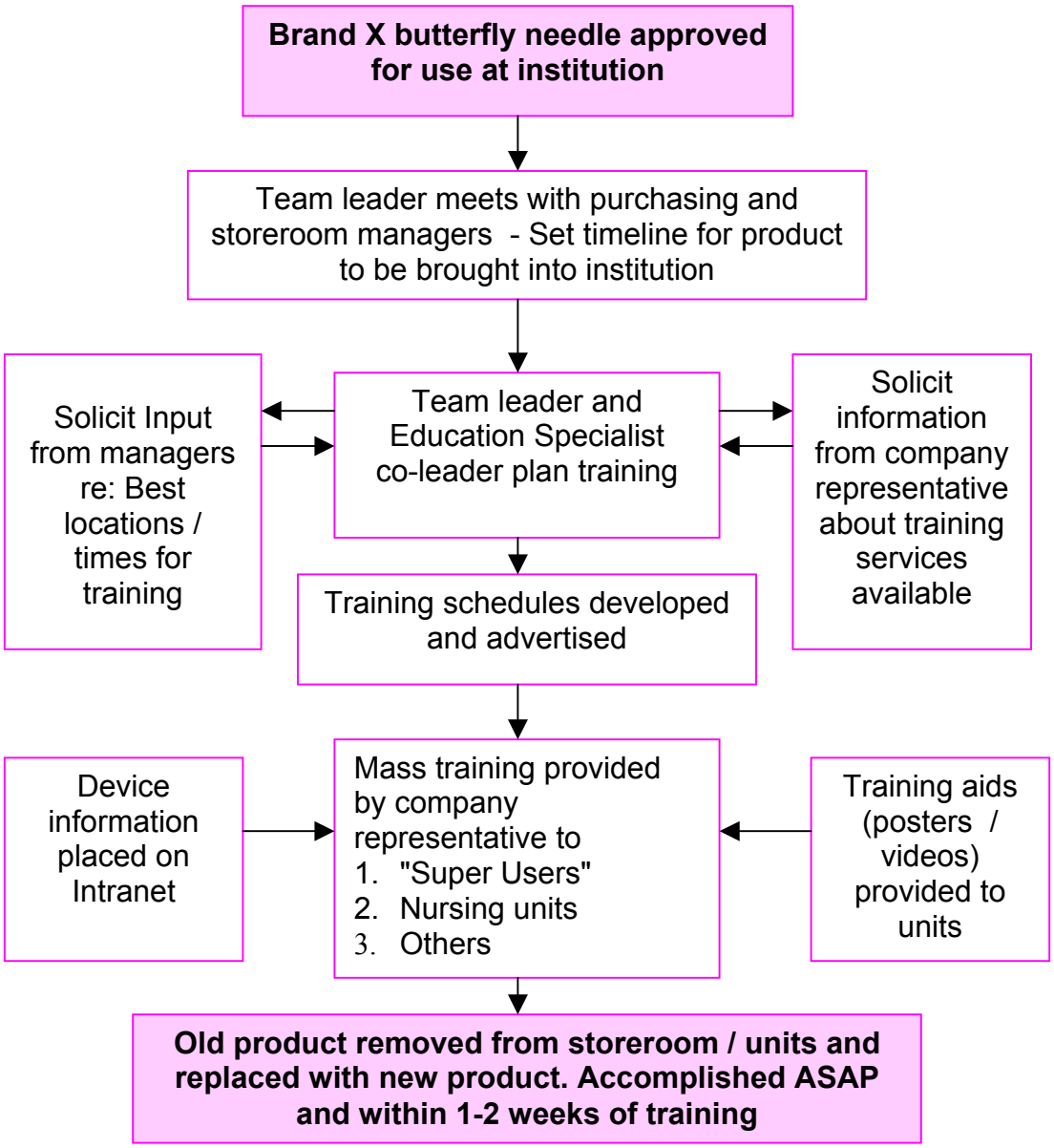


Phase 5: Implement and Monitor the New Device(s)

Facility Description:
Large private, not-for-profit, academic medical center that includes over 950 hospital beds, twelve family health centers, two ambulatory surgical centers, a research institute and an education foundation. Over 2,000,000 outpatient visits and more that 50,000 hospital admissions each year. Facility employs over 1000 physicians representing approximately 120 specialties and subspecialties, approximately 3,000 nurses and a wide range of technical and support staff. Total number of employees is approximately 13,000.

Implementing New Device(s) - Process

Once a device is approved for use we follow a similar process for implementation. The following information about safety butterfly needles (winged needles) demonstrates the process.



Set Timeline
Once the butterfly needle was approved, the team leader met with the purchasing representative and storeroom manager to establish a workable timeline for product introduction. It was important to know when the manufacturer or distributor would be able to provide adequate volume of product to the institution. Training and conversion dates were not set until this information was obtained and guaranteed.

Plan Training
The team felt that planning adequate training was vital to the success of the conversion.

Managers were asked to provide the following information:
- Best time(s) for inservice/training on units
- Best location(s) for inservice/training activities

The company representatives were expected to supply:
- Trainers for the whole institution during a one to two week period (including main campus and all off-campus family health centers and ambulatory clinics).
- 24/7 training to cover off-shifts and weekend staff
- PDF files of training posters for institution's Intranet
- Wall posters for all units
- Videos and instructional pocket cards if available

Training Schedules
Training schedules were developed based on above needs assessment. These schedules were then sent to all involved managers several weeks in advance. A second "reminder" notice was sent out within a week of training. Training times were established to include staff working off-shifts including weekends and nights.

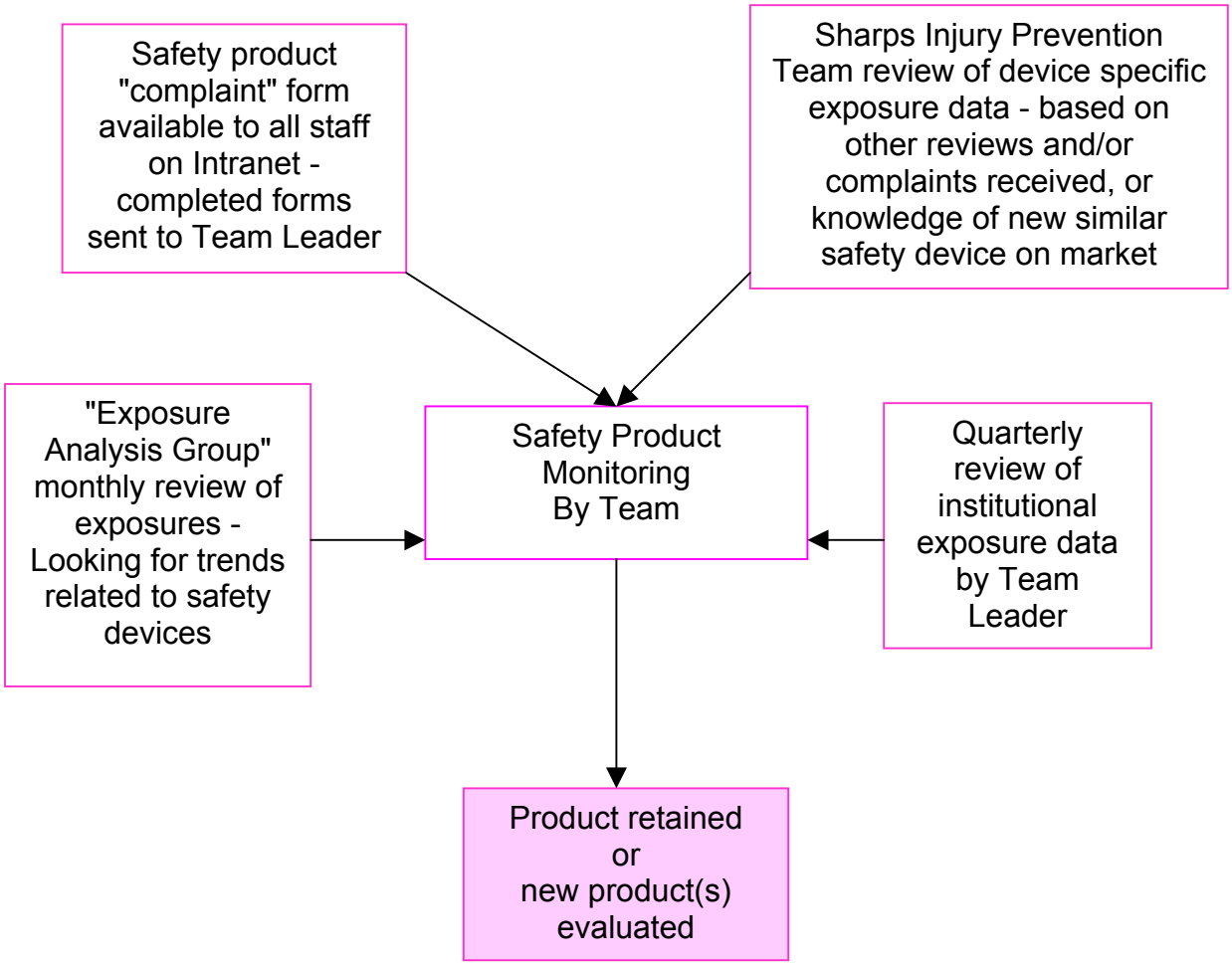
"Super Users"
With such a large number of persons being trained on the safety butterfly needle we developed the "Super User" concept. Each area was asked to name a "Super User". This person would be provided advanced training. The "Super User" could then act as an additional resource to co-workers. "Super Users" were not asked to train, but assist individuals experiencing problems during implementation. "Super Users" were trained at an hour-long session, which include a company sponsored complimentary "luncheon" or "dinner". Attendees were encouraged not to leave until they were comfortable with using the product.

Training Aids
The company was asked to provide any available training aids to each area involved (i.e., wall posters, pocket cards, videos). These items would ensure access to information for staff that may miss formal training sessions. All of the training aids mentioned were provided free of charge for our butterfly needle conversion.

Intranet
The institution's Intranet was used to post PDF files of the company's wall posters. This provided managers with an additional way to access the training information.

Conversion
The old non-safety butterfly needles were replaced in the storeroom within a week of training. Patient unit Omnicell "product delivery" machines were changed out at the same time.

Monitoring Use/Satisfaction
Every new safety device is subject to ongoing monitoring for use acceptability, efficacy, and patient satisfaction. The process is outlined below.



"Product Complaint" Form
A "product complaint" form was developed to provide a method for staff to send in written complaints to the committee. This complaint form is available on the institution's Intranet. Completed forms are sent to the Team Leader for review. Multiple complaints on any single item or a single salient complaint are then reviewed by the team. For example, multiple complaint forms were received from the pediatric department about an IV catheter. This led to a team investigation and replacement of the device from the pediatric arena. After our butterfly needle conversion no complaint forms were received.

A copy of the form is attached. **See addendum # 1**

"Exposure Analysis Group"
Each month a sub-group of the Sharps Injury Prevention Team meets to review the previous month's occupational exposure accident reports. The goal is to look for trends related to activities or devices involved in exposures. In approximately one year the group reviewed a few sharps injuries related to safety butterfly needles. All exposures were related to operator failure to activate the safety device immediately after use. This indicated a need for a passive device. However, no passive butterfly needles are commercially available. All the exposed persons received counseling and/or additional training from their managers.

Quarterly Exposure Data Review
The team leader collates quarterly aggregate exposure data and sends a report to senior administration. Important safety device data from this report is reviewed with the Sharps Prevention Team. We discovered several exposures related to the safety butterfly needle. Most were from operator failure to activate the safety feature. The team wondered if another brand of safety butterfly might be easier to activate than the existing product. The team discovered another active butterfly needle, which allows the safety device to be activated before the needle is removed from the patient. The team is currently in the process of evaluating this device as a possible replacement for the current safety butterfly needle in use.

Difficulties encountered
- Discovery of units that were not included in inservice/training. Training was provided.
- Unit rounds revealed some areas with large stockpiles of old non-safety devices. Removal of old product was necessary in order to gain compliance with use of new safety needles.
- Certain areas called to complain that they were not inserviced on the new butterfly needle. Investigation showed that the representative had shown up but the units were too busy and nurses did not attend.

Lessons Learned

- Make unit rounds to ensure the new products are being used.
- Physically remove any old stock. Do not leave this responsibility to the nursing management. Use team members when possible to make "safety unit rounds".
- Allow time (3-6 months) for most staff to get past the learning curve after introduction of new devices. Critically review any product complaints received in early conversion phase. Complaints about a new product may be related to lack of training or staff "comfort zone" in the early phases rather than from a poor product design.
- Active safety devices will not eliminate all exposures. Be prepared to encounter exposures from failure of users to activate safety device.
- When bringing in a new device expect some delays in delivery. On a few rare occasions we had minor delays in delivery (about 2 weeks or less). These difficulties can be avoided by setting your timeline well ahead to allow for manufacturers and distributors to obtain adequate amounts of product.
- Keep training schedules - use as templates for future training programs.
- **Safety devices can fail!** We have encountered a few exposures related to safety devices that failed to work correctly. The workers thought the device was "safe" and handled the used sharp as though it could not hurt them. Our staff generally uses the term "safety devices". A better descriptive term to use is "SAF**ER** DEVICES."

Estimated staff hours involved in implementation of safety butterfly needle

Type of Staff	Estimated Hours Spent on Implementation of Butterfly Needles
Management	50
Administrative	15
Front-line	1200*
Total	**1265**

Other, non-labor costs
1. Xeroxing schedules

* Includes workers attending 1/2 hour training programs

ADDENDUM #1

ENGINEERED SHARPS INJURY PROTECTION AND NEEDLELESS SYSTEM PRODUCT COMPLAINT FORM

Use this form to document complaints regarding sharps with engineered injury protection and needleless systems (designed to prevent occupational exposures to blood or body fluids) approved for use at (NAME OF INSTITUTION)

PRODUCT*: (Please provide brand name, model number, size, and any other identifying information)*

_____

_____

_____

Date: _____
Name: _____
Title: _____
Department: _____
Phone Number: _____***E-mail:*** _____***Pager:*** _____

Please estimate the number of times you have used this product:

❒ Few (between 1-10 times)
❒ Many (between 10-50 times)
❒ Constantly use (Over 50 uses)

Describe any training you received prior to the use of the product?

❒ Yes / Formal inservice training
❒ Yes / Informal inservice training
❒ No training

Please check any of the following that apply: ***Compared to a traditional device.....***

❒ The safety device has jeopardized my patient's safety
❒ The safety device has jeopardized the success of a procedure being performed
❒ The safety device is not effective in preventing worker exposure incidents
❒ The safety feature interferes with normal use of this product
❒ The safety device takes longer to use than a non-safety device
❒ The safety device has increased the number of sticks to my patients
❒ The safety device causes increased discomfort to my patient
❒ This safety device does not work reliably (has failed more than once)
❒ It is difficult to know if the safety device is activated

Please add any additional information related to your complaint:

_____

_____

_____

_____

_____

_____

_____

_____

Send Form to:
Name of Sharps Injury Prevention Team Leader